Research collaboration and development of intellectual property with the University of Southampton in the field of asthma and COPD

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Abstract

The University of Southampton, one of the UK's top ten research universities, has an active enterprise agenda encompassing commercial licensing, spin-out creation, commercial research collaboration, consultancy and staff development. Southampton aims to be a recognised world leader in its interactions with industry while maintaining the ethos of a leading academic centre of research and teaching excellence. This paper explores the creation of and ongoing relationship between Southampton and Synairgen plc, a spin-out from the University founded on its expertise in the field of asthma and COPD, as a case study of the benefits and balances to be found between academic, enterprise and corporate agendas.

SOUTHAMPTON AND SYNAIRGEN

In June 2003, Synairgen was spun out of the University of Southampton's School of Medicine, founded on intellectual property in the asthma and chronic obstructive pulmonary disease (COPD) field from the Allergy & Inflammation Research Division (AIR) headed by Prof. Stephen Holgate. Synairgen is located in close proximity to the School of Medicine, and its three founding members retain their university positions. Southampton University and Synairgen enjoy a productive and synergistic research relationship where recognition of each other's primary drivers and constraints has enabled positive outcomes for both. In October 2004 Synairgen plc's shares were admitted to trading on the London Stock Exchange's Alternative Investment Market. Synairgen raised £10m (before expenses) and, in order to meet institutional demand, the university sold 400,000 shares for £0.5m, leaving the university with a balance of 3,600,000 shares, representing 16.6 per cent of the issued share capital.

AIR is a highly successful research group which has, for several years, attracted significant levels of industrially sponsored or collaborative work, frequently involving disease-related human tissue and of significant mutual benefit. The scientific attractiveness of such projects to the university and commercial attractiveness to the collaborators is clear and, as ever, such collaborations require careful negotiation and management with respect to differing desires for publication and intellectual property rights. The university was aware, however, that it had significant intellectual property, developed outside such collaborations and using non-commercial funding, the value of which was not being realised through such collaborations. In seeking to balance the university's parallel aims of continued high-ranking research publications, achieving value from exploitation of its know-how and arising IP, and empowering its researchers to reach their

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goals, the university concluded that a spin-out company would be the most effective route. Synairgen's creation has the potential to create substantial value for the university, but has changed the landscape on which collaborative research is conducted by the university in the field of asthma and COPD. Both the university and Synairgen are working to operate to their benefit in this revised landscape and, where appropriate, to work in collaboration.

BALANCING FREEDOM TO OPERATE WITH COMMERCIAL NEEDS

Universities' research rights

A university's research activities may be considered as analogous to a coral reef. Life is concentrated at the outer edges but is built on the accretion of previous activity. If further growth is blocked, the affected area dies, and the contribution of previous years is nullified. Any licence or assignment arrangement which prevents use by a university of its research results or IP kills research activity. While it is now generally accepted practice that universities retain such research rights under most licence and assignment arrangements, there are areas in which this is problematic. Lead contenders in this category are fields of research that inherently tend to involve the use of proprietary research materials, techniques and expertise (or financial support in areas which funding bodies do not address) and therefore involve interactions with commercial entities. Not surprisingly, many exclusive licensees or assignees of intellectual property consider permitting this to be an unacceptable erosion of their rights.

In the arrangements between Southampton and Synairgen the continued activity of the founding scientists in their academic roles, in addition to Synairgen roles, has been a powerful force in helping reconcile these apparently conflicting objectives. Synairgen recognised that it was in its best interests for the university group to remain a vibrant expanding research presence, with the potential to provide further licensable intellectual property and expert collaboration. Equally, the university recognised that it would be imprudent to establish a spin-out and then undermine its business plans by seeking to continue business as normal.

An arrangement was therefore agreed under which the university is able to undertake commercial collaborative work unless it conflicts with Synairgen's interests, and a mechanism is provided to ensure that the university's research goals are not frustrated outright in such circumstances. This arrangement is working well, and the university is pursuing collaborative research projects that would have been impossible in the case of a blanket ban on commercial collaboration, and are of little import to Synairgen. This ability of AIR to conduct collaborative projects with other commercial entities, many of whom have both cutting edge research programmes in this area and a history of collaboration with AIR, is highly significant both for AIR's continued research strength and for the economy of the School of Medicine.

COLLABORATING WITH SYNAIRGEN

As Synairgen is now an independent entity, its dealings with the university must clearly be conducted at arm's length on the same terms as for any other commercial entity wishing to work with the university. Southampton is fortunate in that separate offices deal with commercialisation of intellectual property (Centre for Enterprise and Innovation) and research contracts (Research Support Office). Thus the university staff dealing with contract negotiations for further research contracts are distinct from those who were involved in the setting up of the company, and who may have ongoing involvement in the company. Equally the university has processes for managing conflicts of interest, including where academic staff are employees or directors of contracting companies, which operate to ensure financial transparency and

preserve the interests of the university and especially those of its researchers involved in such programmes but not otherwise linked to such companies.

The ability of Synairgen to invest significantly in developing the platform of technologies originally licensed to them by the university, and to actively market itself and seek further commercial partners, provides a knock-on benefit to the university in terms of additional collaborative projects flowing into the university via Synairgen and from which the university receives appropriate financial recompense and publication benefits.

COLLABORATING WITH THE UNIVERSITY

Part of Synairgen's technical platform is *in vitro* models relevant to asthma and COPD. These models utilise human cells in order to overcome the deficiencies of standard available *in vitro* models for these diseases, which have arguably hampered scientific and medical advance in these fields.

Synairgen's collaboration with Southampton's School of Medicine

In order to access the human materials required for these models, Synairgen has been collaborating with Southampton's School of Medicine to develop Synairgen's biobank of disease-relevant samples. For Southampton, the ability to meet the requirements of the regulations introduced over the past few years relating to clinical trials and samples (ie the UK Department of Health Framework for Research Governance and the Medicines for Human Use (Clinical Trials) Regulations 2004) has been critical to ensuring the continued ability of the university to undertake clinical research, whether investigator or commercially led. The university has worked closely with Southampton University NHS Trust to ensure that the necessary research governance processes are in place and work efficiently. Without the involvement of the School of Medicine's researchers it would be extremely difficult for Synairgen to build this resource by direct interaction with the NHS. Equally, this is an example of how the symbiotic relationship between the University Medical School and the NHS is necessary to enable effective medical research, a factor of which the university must be ever mindful in any collaborative arrangements that it enters into.

DEVELOPING INTELLECTUAL PROPERTY WITH SYNAIRGEN

For the university, Synairgen provides a licensee for further intellectual property in the field where the university can achieve a double win of licensee fees and potentially increased value in its shareholding. Furthermore, there is a reasonable expectation that Synairgen will understand the nature and potential of any such items licensed and be positioned to progress their exploitation effectively. Clearly, in any such licence arrangement the university needs to ensure that it achieves fair market price, and that no university employee is placed in a situation of conflict where they might feel pressured to advise the university inappropriately with regard to the value of such intellectual property.

All too frequently, universities suffer from the too early–too late conundrum with respect to their intellectual property, such that when its invention is patentable, the degree of available proof is insufficient to interest potential licensees, or that once such proof has been obtained, it is either no longer possible to obtain patent protection or the expense of maintaining patent applications can no longer be supported. In the UK, government and venture capital-backed early project development funds have gone some way to assuaging this dilemma; however, a spin-out company with directly relevant expertise and the ability to employ research staff without publication imperatives represents another highly effective means of reducing such intellectual property wastage.

DEVELOPING INTELLECTUAL PROPERTY WITH THE UNIVERSITY

For Synairgen, its contractual arrangements with the university provide a route to obtain licences to further relevant intellectual property developed by the university. In this way Synairgen benefits from a cutting edge to its pipeline, while allowing its research management to concentrate on the later stage research work being carried out on its own programmes. This applies both to product-related opportunities and keeping Synairgen's technical abilities up to date, a vital factor for most companies and particularly those in high-technology areas. Again, for the university this provides a route for effective commercialisation for technical developments that it would otherwise be difficult to obtain significant value from.

Balancing interests

THE RESEARCHER'S PERSPECTIVE

For the university's research employees, whether directly linked to Synairgen or not, the collaborative links with Synairgen provide additional depth to their understanding of the relevance of their work, the operation of the commercial sector and opportunities for progressing their research interests. Such exposure is particularly beneficial to researchers in the early stages of their careers by increasing the scientific and commercial horizon apparent to them and thereby benefiting the overall science base, particularly in the UK where academic and commercial researchers have frequently swum and progressed their careers within separate pools, with little mobility or even understanding between them. Such segregation cannot be beneficial to either science or the economy and all forms of academic–commercial scientific interaction have beneficial potential in this context, regardless of more apparent outputs.

For those involved in the scientific foundation of Synairgen and who have also continued their university work, this dual role provides a further dimension in which our science can be explored, allowing greater total scope of scientific progress. This should not be automatically equated with greater flexibility as the balancing act of our joint responsibilities and the arrangements in place between the company and university can require advanced navigational skills; however, we remain confident that a way through can be found for most issues.

BALANCING INTERESTS WITHIN THE UNIVERSITY

Finally, it is worth touching on the internal compromises made by universities in their interactions with commercial collaborators and licensees. The primary drivers for universities will clearly include scientific value and its recognition through publication, financial returns, both immediate and on any further intellectual property, and the encouragement and facilitation of enterprise activities of its researchers (in the case of the UK in accordance with governmental directives). However, each of these drivers may belong to different individuals or departments/interest groups within that university and some may be relevant to more than one such grouping with conflicting aims. For example, a principal investigator may be more concerned on a given project with keeping a key researcher employed between grants than with publication, but the head of their research division may be more concerned by timely publication for inclusion in the RAE (a publication-based assessment exercise whereby the research excellence ratings of institutes' divisions are determined, forming the basis for future core governmental research grant allocations). Alternatively an investigator may be concerned primarily with publication whereas the administration may be concerned with ensuring that the project will not incur a financial loss.

Universities' individual structures vary in their effects and flexible approaches will operate on a case-by-case basis. It is therefore worth emphasising again that

those entering into collaborative arrangements need to have, and critically communicate both to each other and their legal colleagues, their key objectives in entering into such arrangements, otherwise it is entirely possible to head for a lose–lose situation without either party really understanding how it has happened.